



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/573,138

11/06/2006

David Wallach

30694/41889

3144

4743

7590

04/28/2011

MARSHALL, GERSTEIN & BORUN LLP
233 SOUTH WACKER DRIVE
6300 WILLIS TOWER
CHICAGO, IL 60606-6357

EXAMINER

WEN, SHARON X

ART UNIT

PAPER NUMBER

1644

NOTIFICATION DATE

DELIVERY MODE

04/28/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mgbdoCKET@marshallip.com

Office Action Summary	Application No.	Applicant(s)	
	10/573,138	WALLACH ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-17,19-30,32-56 and 65-83 is/are pending in the application.
- 4a) Of the above claim(s) 17,39-56 and 65-83 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-29 is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11-16,30 and 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment, filed 02/16/2011, has been entered.

Claims 2, 10, 18, 31, 57-64 and 84-85 have been canceled.

Claims 1, 3-9, 11-17, 19-30, 32-56 and 65-83 are pending.

Claims 17, 39-56 and 65-83 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention/species, there being no allowable generic or linking claim.

Claims 1, 3-9, 11-16, 19-30 and 32-38 are currently under examination as they read on a composition or a preparation comprising an antibody that binds a peptide of NIK set forth in SEQ ID NO: 7, 11 or 12, the hybridoma producing the antibody.

This Action will be in response to Applicant's Arguments/Remarks, filed 02/16/2011.

The rejections of record can be found in the previous Office Action, mailed 08/17/2010.

Withdrawn Claim Rejections - 35 USC § 112 first paragraph

The previous Written Description and Enablement rejections under 35 USC 112, first paragraph, for an antibody that binds *any* portion of the amino acid sequences set forth in SEQ ID NO: 7, 11 or 12 for detecting NIK *or a mutein, functional derivative, active fraction, circularly permuted derivative, salt or a portion thereof* has been withdrawn in view of the deletion of the claim language in Applicant's amendment, filed 02/16/2011.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1644

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-9, 11-16, 30 and 32-38 stand rejected under 35 U.S.C. 102(e) as being anticipated by Schreiber et al. (US 6,822,138 B1, see entire document).

Applicant's argument has been considered but has not been found convincing for reasons of record and reiterated herein for Applicant's convenience.

Schreiber taught a polyclonal antibody that binds specifically to NIK (see e.g., column 15, paragraph 4) and a pharmaceutical composition comprising the antibody as a modulator of NIK and a pharmaceutically acceptable carrier (see column 18, lines 41-49 and column 27, lines 32-43).

Although Schreiber et al. did not teach the polyclonal antibody to NIK to bind specifically to the peptides set forth in SEQ ID NO: 7, 11 or 12, given that polyclonal antibodies are known to bind multiple epitopes on one antigen, the prior art polyclonal antibody raised against NIK would necessarily bind to the epitopes comprising the amino acid sequences of SEQ ID NO: 7, 11 and 12.

Since the Office does not have a laboratory to test the prior art polyclonal antibody, it is Applicant's burden to provide objective evidence showing that Schreiber's polyclonal antibody raised against NIK does not bind to SEQ ID NO: 7, 11 or 12.

In response to Applicant's argument that the polyclonal antibody taught by Schreiber would not necessarily bind the epitopes of SEQ ID NOs: 7, 11 and 12 because a polyclonal antibody generated against a portion of a protein will only recognize epitopes within that portion, it is noted that Schreiber's polyclonal antibody is not generated against a portion of NIK but the entire protein, thus the polyclonal antibody would necessarily bind to SEQ ID NOs: 7, 11 and 12 as the epitopes within the protein because polyclonal antibodies bind multiple epitopes.

In response to Applicant's argument of unpredictability of the polyclonal antibodies generated against NIK in that not all polyclonal anti-NIK antibodies detect NIK in a Western blot or immunoprecipitation assay, it is noted that while it is acknowledged that different polyclonal antibodies have different affinity and titer, the sensitivity and specificity of these assays also depend on other factors such as

Art Unit: 1644

secondary antibody and detecting agent. Given that the prior art antibody is a polyclonal antibody against the entire NIK, it would necessarily detect NIK in a Western blot or immunoprecipitation assay. While it is acknowledged that polyclonal antibodies do not inherently bind all epitopes, Applicant has not provided objective evidence to show that a polyclonal antibody taught by Schreiber would not bind epitopes of SEQ ID NO: 7, 11 or 12.

Applicant further pointed out that Schreiber did not reduce to practice the polyclonal antibody. In response, it is noted that "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." (See, *Impax Laboratories Inc.*, 81 U.S.P.Q.2d 1001, 1012, citing *Novo Nordisk Pharms., Inc v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005)). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). See MPEP § 2121.01. It is noted that the level of ordinary skill in the pertinent art would be high enough to make a polyclonal antibody against NIK.

The burden was properly shifted to Applicant to provide objective evidence to show that Schreiber's polyclonal antibody does not bind SEQ ID NOs: 7, 11 and 12. Applicant's amendment has not been found convincing. Therefore, the rejection is maintained for reasons of record as it applies to the amended claims.

Conclusion

Claims 19-29 are allowed.

Claims 1, 3-9, 11-16, 30 and 32-38 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Huynh N. Phuong can be reached on (571)272-0846. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Primary Examiner, Art Unit 1644